



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentees: Catherine Anne Abbott et al. )  
Patent No. 6,881,564 )  
Granted: April 19, 2005 )  
For: DIPEPTIDYL PEPTIDASES )  
Examiner: Sheridan Swope )  
Art Unit: 1652 ) Attorney Docket No. FCSB-100

**REQUEST FOR RECONSIDERATION  
OF PATENT TERM ADJUSTMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The patentees of the above-identified U.S. Letters Patent request reconsideration of the present Patent Term Adjustment of 163 days.

**I. Statement of Facts**

1. The correct Patent Term Adjustment should be 283 days.
2. The Examiner's Amendment (Exhibit A hereto) mailed together with Notice of Allowance on December 10, 2003 (Exhibit C hereto) introduced typographical errors in the claims.
3. A Rule 312 Amendment (Exhibit B hereto) was timely filed to correct these errors.
4. Response to the Rule 312 Amendment, entering the requested corrections, was mailed by the U.S. Patent and Trademark Office on February 7, 2005 (Exhibit C hereto).
5. The above-identified patent is not subject to a Terminal Disclaimer.
6. There have been no circumstances that constitute a failure by the applicants to engage in reasonable efforts to conclude the processing or examination of the application that matured into the above-identified patent.

05/13/2005 WABDEL3 00000095 6881564

01 FC:1455 200.00 DP

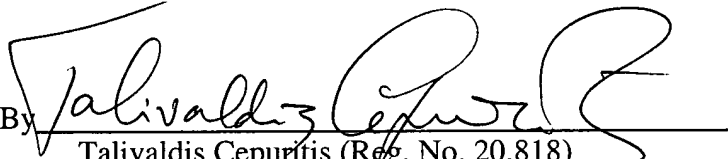
## II. Argument

The Rule 312 Amendment in the present case was necessitated by the actions of the Examiner rather than through any fault of the applicants. Accordingly, the applicants are entitled to a Patent Term Adjustment of 283 days, and should not be charged with a four-month delay when seeking to correct the Examiner's typographical errors in the patent claims.

A check in the amount of \$200.00 to cover the fee under 37 C.F.R. 1.18(e) is enclosed. Kindly charge any fee deficiency or credit any overpayment to our Deposit Account No. 15-0508.

Respectfully submitted,

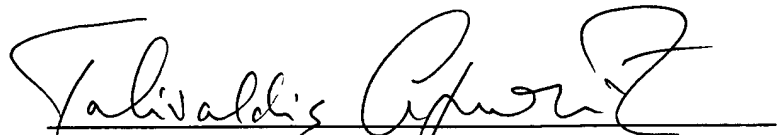
May 10, 2005

By   
Talivaldis Cepuritis (Reg. No. 20,818)

OLSON & HIERL, LTD.  
20 North Wacker Drive  
36th Floor  
Chicago, Illinois 60606  
(312) 580-1180

### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to:  
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 10, 2005.

  
Talivaldis Cepuritis (Reg. No. 20,818)



# Notice of Allowability

## Application No.

10/070,464

## Examiner

Sheridan L. Swope

## Applicant(s)

ABBOTT ET AL.

## Art Unit

1652

### -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amdt filed 03 Sep 2003.
2. ☒ The allowed claim(s) is/are 1,4-9 and 24.
3. ☒ The drawings filed on 18 July 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |  |  |
|--|--|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____               | 6 <input type="checkbox"/> Examiner's Amendment/Comment                    |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9 <input checked="" type="checkbox"/> Other signed ISR.                    |

# EXHIBIT A

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On page 1, insert the following as the first paragraph:

The application is a US 371 National Stage filing of PCT/AU00/01085 filed September 11, 2000 and claims the benefit of priority to Australian applications PQ 5709 filed February 18, 2000 and PQ 2762 filed September 10, 1999.

Cancel Claims 10-23 and 25-27.

Replace Claim 1 with:

1. An isolated peptide which comprises:
  - (a) the sequence shown in SEQ ID NO: 1; or
  - (b) a sequence which has at least 95% identity with the sequence shown in SEQ ID NO: 1, and which has dipeptidyl peptidase activity, with the same substrate specificity, as SEQ ID NO: 1.

Replace Claim 4 with:

4. A fragment of the sequence shown in SEQ ID NO: 1 which has dipeptidyl peptidase activity, with the same substrate specificity, as SEQ ID NO: 1.

Replace Claim 5 with:

5. A fragment, according to claim 4, which consists of the sequence shown in SEQ ID NOs: 3 or 5.

Replace Claim 8 with:

8. A fusion protein comprising the amino acid sequence shown in SEQ ID NO: 1 linked with a further amino acid sequence, the fusion protein having dipeptidyl peptidase activity, with the same substrate specificity, as SEQ ID NO: 1.

Authorization for this examiner's amendment was given in a telephone interview with Talivaldis Cepuritis on November 4, 2003.

***Allowable Subject Matter***

Claims 1, 4-9, and 24 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected Claims, 1, 4-9, and 24, are limited to isolated polypeptides derived from SEQ ID NO: 1. The utility of the polypeptide of SEQ ID NO: 1, as being a serine protease that has dipeptidyl peptidase activity, is credible based on homology to known proteins (Qi et al, 2002) as well as expression in heterologous host cells and analysis by an enzymatic assay (pg 29, line 23- pg 30, line 24; Fig 7; Tables 1 and 2).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

**Sheridan Lee Swope, Ph.D.**

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FEDERAL BUREAU OF INVESTIGATION  
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R. L. Ruff



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Catherine Anne Abbott et al. )  
Application No. 10/070,464 )  
Filed: July 18, 2002 ) Notice of Allowance  
For: DIPEPTIDYL PEPTIDASES ) Dated: 12/10/2003  
Examiner: Sheridan Swope )  
Art Unit: 1652 ) Attorney Docket No. FCSB-100

**AMENDMENT UNDER RULE 312**

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

ENTERED  
KF

Sir:

Kindly amend this application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks** begin on page 3 of this paper.

**EXHIBIT B**

**Amendments to the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claim 1 (currently amended): An isolated peptide which comprises: ~~comprises~~:

- (a) the sequence shown in SEQ ID NO:1; or
- (b) a sequence which has at least 95% identity with the sequence shown in SEQ ID NO:1, and which has dipeptidyl peptidase activity, with the same substrate specificity, as SEQ ID NO:1.

Claims 2-3 (canceled).

Claim 4 (previously presented): A fragment of the sequence shown in SEQ ID NO:1 which has dipeptidyl peptidase activity, with the same substrate specificity, as SEQ ID NO:1.

Claim 5 (previously presented): A fragment according to claim 4, which consists of the sequence shown in SEQ ID NOs: 3 or 5.

Claim 6 (original): A peptide according to claim 1, wherein an asparagine residue in the peptide is not linked to a carbohydrate molecule.

Claim 7 (original): A peptide according to claim 1, wherein the peptide is not expressed on the cell surface membrane of a cell.

Claim 8 (currently amended): A fusion protein comprising the amino acid sequence shown in SEQ ID NO:1 linked with a further ~~further~~ amino acid sequence, the fusion protein having dipeptidyl peptidase activity, with the same substrate specificity, as SEQ ID NO:1.

Claim 9 (original): A fusion protein according to claim 8 wherein the further amino acid sequence is selected from the group consisting of GST, V5 epitope and His tag.

Claims 10-23 (canceled).

Claim 24 (original): A composition comprising a peptide according to claim 1.

Claims 25-27 (canceled).



Application No. 10/070,464 - - - - - 3

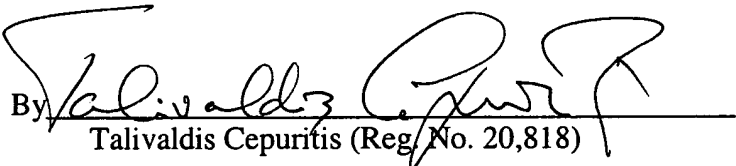
**Remarks**

Claims 1, 4-9 and 24 are allowed. Claims 1 and 8 are amended in order to correct minor typographical errors introduced into the claims by an Examiner's Amendment. The foregoing amendment does not affect the scope of the invention.

Entry of the amendment is respectfully requested.

Respectfully submitted,

March 10, 2004

By   
Talivaldis Cepuritis (Reg. No. 20,818)

OLSON & HIERL, LTD.  
20 North Wacker Drive  
36th Floor  
Chicago, Illinois 60606  
(312) 580-1180



THE UNITED STATES PATENT OFFICE IS REQUESTED TO IMPRESS ITS STAMP ON THIS CARD AND PLACE SAME IN THE OUT-GOING MAIL TO SHOW THE FOLLOWING PAPERS HAVE BEEN RECEIVED.

**AMENDMENT UNDER RULE 312 (3 pp.)**

TC:ps2  
(FCSB-100)

Applicant(s): Catherine Anne Abbott et al.  
Appln. No. 10/070,464  
Filed: July 18, 2002  
For: DIPEPTIDYL PEPTIDASES  
Examiner: Sheridan Swope  
Art Unit: 1652

Mailed: March 10, 2004 (Express Mail mailing label No. EL244341984US)  
Due: March 10, 2004

EL244341984US



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10/070,464

DIPEPTIDYL PEPTIDASES

Application Data	Transaction History	Image File Wrapper	Patent Term Adjustments	Continuity Data	Foreign Priority	Published Documents	Fees	Address & Attorney/Agent
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## Patent Term Adjustment (PTA) for Application Number: 10/070,464

	Days
Filing or 371(c) Date: 07-18-2002	USPTO Delay (PTO): 283
Issue Date of Patent: 04-19-2005	Three Years: -
Pre-Issue Petitions (days): +0	Applicant Delay(APPL): 120
Post-Issue Petitions (days): +0	Total PTA: 163
USPTO Adjustment(days): +0	Explanation Of Calculations

## Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
04-19-2005	Patent Issue Date Used in PTA Calculation	283	
03-16-2005	Receipt into Pubs	↑	
03-14-2005	Dispatch to FDC	↑	
03-14-2005	Application Is Considered Ready for Issue	↑	
03-02-2005	Receipt into Pubs	↑	
02-28-2005	Mail Miscellaneous Communication to Applicant	↑	
02-22-2005	Miscellaneous Communication to Applicant - No Action Count	↑	
02-07-2005	Mail Response to 312 Amendment (PTO-271)	↑	
02-04-2005	Response to Amendment under Rule 312	↑	
08-09-2004	Receipt into Pubs	↑	
06-10-2004	Receipt into Pubs	↑	
05-26-2004	Sequence Forwarded to Pubs on Tape	↑	
03-10-2004	Issue Fee Payment Verified	↑	
03-10-2004	Amendment after Notice of Allowance (Rule 312)	↑	120
03-10-2004	Workflow incoming amendment IFW	↑	
03-10-2004	Issue Fee Payment Received	↑	
02-06-2004	Workflow - File Sent to Contractor	↑	
02-06-2004	Receipt into Pubs	↑	
12-10-2003	Mail Notice of Allowance	↑	
11-14-2003	Issue Revision Completed	↑	
11-14-2003	Notice of Allowance Data Verification Completed	↑	
11-14-2003	Notice of Allowability	↑	
11-13-2003	CRF Is Good Technically / Entered into Database	↑	
09-27-2003	Date Forwarded to Examiner	↑	
09-05-2003	CRF Does Not Match Application Specification - Applicant Must Correct	↑	
08-27-2003	Response after Non-Final Action	↑	
05-27-2003	Mail Non-Final Rejection	↑	
05-27-2003	Non-Final Rejection	↑	
04-23-2003	Request for Foreign Priority (Priority Papers May Be Included)	↑	
03-27-2003	Date Forwarded to Examiner	↑	
03-21-2003	Response to Election / Restriction Filed	↑	
02-21-2003	Mail Restriction Requirement	↑	
02-21-2003	Requirement for Restriction / Election	↑	
01-21-2003	Case Docketed to Examiner in GAU	↑	
10-22-2002	Application Dispatched from OIPE	↑	
10-17-2002	IFW Scan & PACR Auto Security Review	↑	
10-15-2002	Notice of DO/EO Acceptance Mailed	↑	
07-18-2002	Payment of additional filing fee/Preexam	↑	
07-18-2002	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	↑	

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EXHIBIT C